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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,244	04/01/2004	Steven J. Soldin	31603-2049	6946

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EXAMINER	
SODERQUIST, ARLEN	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
01/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/814,244	SOLDIN, STEVEN J.	
	Examiner	Art Unit	
	Arlen Soderquist	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what elements constitute any of the three trademarked spectrometers. Additionally it is not clear if the claim would cover someone that has modified their spectrometer. Additionally, a trademark identifies a manufacturer or a producer, not a product.

2. Claims 31-32 provide for the use of a mass spectrometer to analyze a sample containing at least two antiretroviral drugs from at least two classes of antiretroviral drugs, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

3. Claims 31-32 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-32 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Volosov (Clinical Biochemistry March 2002). In the paper Volosov presents a simple rapid method for quantification of antiretrovirals by liquid chromatography-tandem mass spectrometry. In the simple, fast and universal method developed, quantification of any combination of the 15 currently marketed anti-HIV drugs in human plasma is possible, using liquid chromatography-tandem mass spectrometry. The sample preparation section on page 100 teaches that an 80-μL plasma sample was spiked with internal standard (cimetidine), and protein was precipitated with 200 μL MeCN (acetonitrile). The sample was centrifuged and 30 μL aliquot was injected onto the HPLC column, where it underwent an online extraction (sample cleaning) with NH4OAc

(ammonium acetate, see LC/MS/MS procedure section on page 101). The automatic switching valve was then activated, changing the mobile phase to MeOH and thereby eluting the analytes into the tandem mass spectrometer. Page 100 teaches the mass spectrometer as an API-2000 spectrometer. Stavudine, zidovudine (AZT) and efavirenz were analyzed in the negative ionization mode, while all the other drugs were analyzed in the positive ionization mode (see Table 4). Page 101 teaches that analytes were quantified by multiple reaction monitoring. The high selectivity of a tandem mass analyzer allowed determination of any combination of the drugs within a 4.5-minute run. Between-day precision was <10% for all the analytes at the concentrations tested. Accuracy ranged 95%-105%. The method was linear over the measuring ranges of all the analytes. Within-run precision gave a coefficient of variation of <7% for all the analytes. Good correlation with other analytical methods was observed. The simplicity, universality and high throughput of the method make it suitable for application in a clinical lab. The materials and method section teaches the preparation of standards and serum or plasma quality control specimens.

6. Claims 1-2, 4-8, 10, 19, 21-22, 24-26 and 31-32 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Shoup. In the paper Shoup teaches simultaneous determination of six protease/reverse transcriptase inhibitors in human plasma utilizing LC/MS/MS. With the success of "combination therapies" using reverse transcriptase inhibitors, antiinfectives, and protease inhibitors in the treatment of HIV infection, BAS Analytics developed a single method for profiling six protease/reverse transcriptase inhibitors in human plasma. The method utilizes robotic solid phase extraction at neutral pH and is generally applicable to all the analytes and their internal standards. Page 19 gives the specifics on the tandem mass spectrometer. Page 21 gives data on the standards used.

7. The information disclosure statement filed August 15, 2007 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each

document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered unless the reference is listed on a PTO-892 Form.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art relates to mass spectrometry of compounds, some of which anticipate the instant claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Arlen Soderquist
Primary Examiner
Art Unit 1797